AR201-13894

Jessica Sandler <jessicas@peta.org> on 08/01/2002 10:38:09 AM

To: NCIC OPPT/DC/USEPA/US@EPA, ChemRTK HPV/DC/USEPA/US@EPA, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, wjones@pinechemicals.org

cc:

Subject: Public comments

Attached please find the comments of the American animal protection community on the PCA's HPV test plan.

Jessica Sandler, MHS
Federal Agency Liaison
People for the Ethical Treatment of Animals
757-622-7382 ext. 1304
jessicas@peta.org
www.peta.org

- HPV test plan comments -- Fatty Acid Dimer.pdf

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

July 30, 2002

Christine Todd Whitman, Administrator
U. S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N. W.
Washington, DC 20460

Subject: Comments on the Pine Chemicals Association's HPV Test Plan for Fatty Acid Dimers and Trimer

Dear Administrator Whitman:

The following comments on the Pine Chemicals Association's (PCA) test plan for the category fatty acid dimers and trimer are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The PCA's test plan and robust summaries for fatty acid dimers and trimer are well-presented. Dimer acids are used in the production of resins for adhesives, printing inks, and packaging. PCA has formed an appropriate category. However, this test plan calls for two inappropriate animal tests with C-18 unsaturated dimers ("dimer"): an aquatic toxicity test with fish and a developmental toxicity test. Conducting these two tests would result in the suffering and death of approximately 650 animals.

This test plan violates the October 1999 agreement among the EPA, industry, animal protection, health, and environmental organizations, and the December 2000 *Federal Register* notice which state, in part:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

8. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.

As in its previous test plans for the tall oil fatty acids category, the tall oil and related substances category, the rosins category, and the rosin salts category, the

PCA is yet again proposing irrelevant aquatic toxicity tests on fish. We ask that the consortium replace this test with another method, such as ECOSAR or TETRATOX. Testing fatty acid dimers and trimer on fish is especially inappropriate given the fact that their extremely low solubility and lack of hydrolyzable functional groups hinder the ability to conduct aquatic tests.

PCA acknowledges the limitations of testing dimer in aquatic environments and therefore proposes to manipulate experimental conditions to enhance solubility. The PCA does not describe how it intends to alter the OECD test guidelines, but does raise the possibility that the experimental conditions themselves "may cause non-specific toxicological effects." This is inappropriate, confounds the experimental results and leads to difficulty in interpretation. The EPA should reject this particular proposal for irrelevant animal testing.

We disagree with Environmental Defense's comments on this proposed test plan: testing for the reproductive endpoint in this screening level program has clearly been met through prior repeat dose testing on animals. Further, in the interests of sparing the lives of the 600 animals who will be killed if the PCA carries out the OECD combined reproductive/developmental toxicity screening study (OECD 421), as proposed, we ask that you instead conduct an *in vitro* test for embryotoxicity (a critical endpoint in developmental toxicity) using the rodent Embryonic Stem Cell Test (EST) protocol that has been validated by the European Centre for the Validation of Alternative Methods (ECVAM). For additional information, please refer to Genschow E *et a*l.: "The ECVAM international validation study on *in vitro* embryotoxicity tests: results of the definitive phase and evaluation of prediction models" *(Alternatives to Laboratory Animals* 30: 151-76, 2002). If a positive result is found, the substance should be treated as a developmental toxicant/teratogen and no further testing should be conducted.

Thank you for your attention to these comments. I can be reached at 757-622-7382, ext.1304, or via e-mail at *jessicas@peta.org*.

Sincerely,

Jessica Sandler, MHS
Federal Agency Liaison